K070464

MAR 16 2007

510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of 21 CFR Part 807.92.

Date: Dec. 27, 2006

1. Company and Correspondent making the submission:

Name – CyberMed, Inc.
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Telephone – +82-2-3397-3970
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Contact – Mr. Song Nak Choi/ Manager

2. Device :

Trade/proprietary name	: OnDemand3D™
Common Name	: Picture archiving and communications system
Classification Name	: Picture archiving and communications system

3. Predicate Devices :

Manufacturer:	: TIS Inc.
Device:	: APAX™
510(k) Number:	: K032760 (Decision Date – 09/17/2003)
Manufacturer:	: MATERIALISE N.V.
Device:	: SimPlant System
510(k) Number:	: K033849 (Decision Date – 05/25/2004)
Manufacturer	: MEVISYS, Co., Ltd.
Device	: VOXELPLUS™ PACS
510(k) Number	: K022692 (Decision Date – 10/11/2002)

4. Classifications Names & Citations :

21CFR 820.2050, LLZ, Picture archiving and communications system, Class2

5. Description :

1) General Description

OnDemand3D™ is a personal computer based dental imaging software which loads DICOM images taken from CT, MR and provides 3D visualization and 2D analysis, various MPR (Multi-Planar Reconstruction) functions for further rapid and precise diagnosis.

OnDemand3D™ is designed to provide users easy and familiar user-interface. Also OnDemand3D™ makes it possible to manage medical images more easily and provides advanced tools for 2D and 3D analysis with various rendering functions. The main functions of OnDemand3D™ are as follows.

2) Main Function

(1) DBM(Data base Manager)

You can use DICOM images stored in Master database, Local databases or Remote PACS servers more conveniently with user-familiar interface such as Window explorer. DBM supports CD-R/RW to keep necessary DICOM images in CD directly. DBM supports to make multiple Local databases so it is very convenient for multiple users on one system.

(2) LightBox

LightBox supports to load different types of DICOM images such as 8/12/16 bits gray images and color images. LightBox provides 'CINE Player' to display multi-frame DICOM images. LightBox supports a preview image on Window print and DICOM print screen.

(3) Dental Reformat

Dental Reformat makes it possible to reconstruct Panoramic and Cross sectional images. Conventional imaging solutions are supported, and also new imaging solutions such as Volume Rendering, 3D Scout and so on are supported. The layout and images are optimized for Reporting.

(4) 3D

3D makes it possible to switch rendering mode such as VR(Volume Rendering), MIP/MinIP, and etc. more easily and conveniently. 3D provides more accurate images by using various rendering functions such as MPR Rotating, Curve, 3D Zoom, Clip, etc.

(5) X-ray Generation

X-ray Generation makes it possible to create X-ray images for cephalometric analysis. Lateral X-ray image and frontal X-ray image can be generated in X-ray Generation module.

(6) Report

Report makes it possible to make a report more easily by using intuitive user interface and also export it to HTML format document. You can capture necessary images on all screens of OnDemand3D™ with Pane-Capture/Region-Capture function and insert the captured images to Report very easily.

3) Information of the image format

OnDemand3D™ can load only DCM files and save results as DCM, BMP and JPG files.

- DCM : DICOM (Digital Image Communication in Medicine) is a Standard Protocol to exchange and transfer the data acquired by Medical Image devices such as a CT, MR, 3D US, etc. It is designated as a Standard Protocol by ACR-NEMA (American College of Radiology-National Electrical Manufacturers Association) and now adopted by most Medical Imaging Devices. OnDemand3D™ 2.0 is adaptable technically for all data of DICOM 3.0.

  Reference : Digital Imaging and Communications in Medicine (DICOM) ACR-NEMA Standards Publication PS 3.1~PS 3.16 2003.
- BMP : The standard bit-mapped graphics format used in the Windows environment. By convention, graphics files in the BMP format end with a BMP extension. BMP files store graphics in a format called device-independent bitmap (DIB).
- JPG/JPEG : Short for "Joint Photographic Experts Group", the original name of the

committee that wrote the standard. JPG is one of the image file formats supported on the Web. JPG images support 16 million colors and are best suited for photographs and complex graphics.

4) Compression

- Compression Method : Lossless Compression

6. Indication for use :

The OnDemand3D™ is intended for use as a software package which loads DICOM images from CT, MR, X-Ray, stores those and provides 3D visualization and 2D analysis, various MPR (Multi-Planar Reconstruction) functions for further rapid and precise diagnosis.

7. Comparison with predicate device :

CyberMed, Inc., believes that the OnDemand3D™, Picture archiving and communications system is substantially equivalent to APAX™ of TIS, Inc., SimPlant System of MATERIALISE N.V. and VOXELPLUS™ PACS of MEVISYS, Co., Ltd..

8. Conclusions :

In accordance with the Federal Food, Drug and Cosmetic Act, 21 CFR Part 807 and based on the information provided in this premarket notification CyberMed, Inc. concludes that OnDemand3D™ is safe and effective and substantially equivalent to predicate devices as described herein.

9. CyberMed, Inc. will update and include in this summary any other information deemed seasonably necessary by the FDA.

END

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

CyberMed, Inc.
c/o Mr. Marc M. Mouser
Senior Project Engineer/Program Reviewer
2600 NW Lake Road
CAMAS WA 98607

MAR 16 2007

Re: K070464
Trade/Device Name: OnDemand3D™
Regulation Number: 21 CFR §892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: January 31, 2007
Received: February 16, 2007

Dear Mr. Mouser:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

K070464

Indications for Use

510(k) Number(if known): K070464

Device Name: OnDemand3D™

Indications for Use:

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Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (Part 21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation(ODE)

David A. Lagman
(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K070464